

EXHIBIT 15

CONFIDENTIAL

Expert Analysis: Lacey R. Keller

- a. Association of Certified Fraud Examiners (ACFE) Global Fraud Conference (forthcoming: 2019)
- b. NASAA Investment Adviser Training (2017, 2019)
- c. Association of Certified Fraud Examiners (ACFE) Law Enforcement and Government Anti-Fraud Summit (2018)
- d. PLI Hedge Fund and Private Equity Enforcement & Regulatory Developments 2018 (2018)

20. My CV is attached as Exhibit 1.

C. Remuneration

21. Gryphon is being compensated for its time and expenses. My hourly rate is \$475 per hour. Other Gryphon personnel working on this matter have billing rates of \$275 to \$375 per hour.

D. Scope of Report

22. This report focuses specifically and exclusively on manufacturers' anti-diversion and suspicious order monitoring programs. Throughout the report, I will refer to labelers and manufacturers interchangeably as the entities that create the drugs analyzed.

23. I have been asked to report the results of applying certain compliance metrics applicable to manufacturers to prescribers.

24. I have been asked to report the results of applying certain compliance metrics applicable to a manufacturer to pharmacies and physicians.

25. I have been asked to trace the orders made by distributors that were deemed peculiar by a manufacturer to the end pharmacy buyer through that manufacturer's chargeback data.

26. I have been asked to report the impact on opioid prescribing in Summit and Cuyahoga County if a small labeler had reported the activity of suspicious prescribers.

E. Summary of Opinions

27. My findings demonstrate that there were millions of prescriptions and purchases of billions of dosage units and MMEs in Cuyahoga and Summit counties that defendant manufacturers of opioids (called labelers) could have identified as being of unusual size or frequency and deviating from the normal pattern yet were unreported. I found that defendant labelers purchased external data sources (IQVIA) and maintained internal data sources (chargebacks, 867 data, sales data) that provided them with granular information regarding the entity distributing, prescribing, and purchasing their opioid products. All defendant labelers purchased IQVIA Xponent data. All of this information was sufficient to support a Suspicious Order Monitoring (SOM) program identifying problematic distributors, prescribers and pharmacies. In particular, it was and is possible using

standard data-analytic tools to determine from the data that the defendant labelers had in their possession suspicious prescribing and purchasing patterns, and to identify particular physicians and particular pharmacies with problematic prescribing patterns.

28. I found that defendant labelers purchased robust external data sources and maintained internal data sources that provided them with granular information regarding the entity distributing, prescribing, and purchasing their opioid products. This information was sufficient to support a Suspicious Order Monitoring (SOM) program identifying problematic prescribers and pharmacies. Nonetheless, defendant labelers did not implement robust monitoring programs and therefore failed to capture a substantial volume of potentially suspicious transactions.

29. Although all defendant labelers purchased IQVIA Xponent® data, each used it to monitor potential inappropriate prescribing in different ways to differing degrees. Teva and Mallinckrodt, for example, committed to regularly monitor IQVIA Xponent as agreed to with the FDA in their Risk Monitoring Plans (RMP), also known as Risk Minimization Action Plans (RiskMAP).¹ However, the details of how that data analysis would take place and what actions it would lead to was unspecified. To my knowledge only one defendant, Purdue Pharma, used IQVIA in a programmatic or algorithmic way². Implementing Purdue's calculations, however, requires additional data that has not been made available to me.

30. Furthermore, instead of using this data to develop monitoring programs, defendants used it to inform their targeted marketing efforts to prescribers and evaluate drug performance. Similarly, despite the scope and detail of the chargeback data they maintained, defendant labelers did not use that data programmatically or effectively to capture suspicious activity among end buyers.

31. To quantify the prescriptions or transactions that labelers could have readily detected were of unusual size or frequency, I applied a series of compliance metrics to each dataset. Defendant labelers and distributors originally developed all but one of these compliance metrics. Among these metrics were whether the volume prescribed or ordered was over a certain static threshold; whether a buyer significantly increased prescriptions or purchases relevant to their own histories; or how prescriptions or purchases compared to national averages for the same labeler opioid product. I then applied these compliance metrics to physicians and pharmacies to determine what suspicious activity could be detected by labelers. The last metric was derived from labeler defendants' due diligence Standard Operating Procedures documents in which companies expressed concern that pharmacies may be purchasing large quantities of controlled substances from more than one distributor as a means of staying below distributor thresholds. Manufacturers were uniquely positioned to identify end-customers' purchasing patterns and, thus, which customers were using multiple distributors.

32. In Part One of this report, I analyzed the prescribing history of physicians from a labeler's perspective. As previously noted, this analysis relied on IQVIA Xponent® data, which was often purchased by defendant labelers for marketing purposes. In fact, this dataset was produced

¹TEVA_CHI_00049296, MNK-T1_0007204156

² PDD1503450011

through discovery to plaintiffs by one of the defendant labelers.³ By using these compliance metrics, I demonstrated that defendant labelers did not detect millions of prescriptions that could have signaled irregular prescribing patterns. In some cases, labelers even targeted these high-volume prescribers for prescriptions of their product instead of reporting their prescribing patterns as suspect.⁴ I found several examples of high opioid-prescribing physicians whose suspicious prescribing could have been evident but, to the best of my knowledge, were not reported by defendant labelers.

33. Part Two of this report analyzed chargeback data. Chargebacks are requests submitted by distributors to labelers to protect distributors from profit loss when drugs are sold to a buyer at less than the distributor paid the labeler for them.⁵ Order information – including drug, dosage, package quantity – is contained in the request to demonstrate to the labeler that the opioid product was sold for a lesser value to an end buyer, such as a pharmacy. Because of this system, defendant labelers regularly received chargeback requests from distributors regarding purchases of specific national drug code (NDC) products. This gave the labelers access to information regarding the purchasing patterns of their downstream customers. With this data, I demonstrated that labelers had precise insight into pharmacies in Summit and Cuyahoga that were ordering excessive amounts of their opioid products. Using chargeback data alone, labelers could have detected the suspicious activity of pharmacies, and had they reported them, they would have stopped hundreds of millions of dosage units from being dispensed in Summit and Cuyahoga counties.

34. I was asked by plaintiffs' counsel to include additional analysis that examined what would have happened if a labeler with a comparatively small market share had reported and stopped supplies to suspicious prescribers. I demonstrated that if Janssen – the defendant labeler with the second smallest market share in Summit and Cuyahoga counties – had reported suspicious activity, prescriptions for millions of dosage units could have been stopped in Summit and Cuyahoga counties.

35. The results of my analysis are stark: had the defendant labelers applied similar analytic techniques using their own compliance metrics, that analysis would have identified suspicious orders in Cuyahoga and Summit counties responsible for millions of opioid prescriptions and billions of MMEs, as shown below in Tables 8 through 11. In the aggregate, suspicious orders that defendant labelers could have identified, but apparently did not, were responsible for *more than* half of all opioid prescriptions filled in Summit and Cuyahoga Counties in the periods 1997-2006 and 2008-2017, and for nearly half the MMEs dispensed there in that same period. My analysis also shows that closer analysis of the flagged prescriptions would have confirmed that multiple, identified doctors in Summit and Cuyahoga counties, not limited to those profiled in this report, were engaged in highly suspicious and likely improper prescribing. Similar, closer analysis of flagged pharmacies would have identified specific, identified highly problematic pharmacies. This analysis shows that it is and was possible to identify by name the problematic doctors and

³ ALLERGAN_MDL_02485011

⁴ MNK-T1_0001029479

⁵ PPLP004397849

pharmacies in Summit and Cuyahoga counties in this period. Using the defendant labelers' own metrics, it was not at all difficult to identify where opioids were being used problematically and where diversion was a concern. Labelers just needed to look.

F. Materials Reviewed

36. The following documents and data were considered for this report. The staff that worked under my direction had full and complete access to the documents and data produced in this case. They were as follows:

- a. Automation of Reports and Consolidated Orders System (ARCOS) electronic data, received from the DEA and processed by Securities Litigation and Consulting Group, Inc. (SLCG) on or about April 5th, 2019;⁶
- b. IQVIA (formerly Quintiles and IMS Health, Inc.) Xponent® data produced to plaintiffs' counsel through ALLERGAN_MDL_02485011 for years 1997-2006, 2008-2017 (there was no data file for 2007);
- c. Chargeback and/or 867 data data from all defendant labelers through thousands of files in different formats (e.g., .csv, .txt, .xlsx, .pdf). The Bates stamps for reviewed documents are shown below by labeler, is shown in the table below;

Figure 1 Bates Numbers of Defendant Labeler Data

Labeler Name	Data Source
ENDO	ENDO_DATA-OPIOID_MDL-00000042; ENDO_DATA-OPIOID_MDL-00000044 - ENDO_DATA-OPIOID_MDL-00000084
PAR	PAR_OPIOID_MDL_0001596821 - PAR_OPIOID_MDL_0001596826
QUALITEST	PAR_OPIOID_MDL_0002016651 - PAR_OPIOID_MDL_0002016659; PAR_OPIOID_MDL_0002016661 - PAR_OPIOID_MDL_0002016726
JANSSEN	JAN-MS-03108830 ⁷
MALLINCKRODT	MNK-T1_0007965587 - MNK-T1_0007965588
PURDUE	PPLP004418578 - PPLP004422062; PPLP004422064 - PPLP004422150
ACTAVIS	ACQUIRED_ACTAVIS_02001522; ACQUIRED_ACTAVIS_01996164 - ACQUIRED_ACTAVIS_01996173
ALLERGAN	ALLERGAN_MDL_03303052_001; ALLERGAN_MDL_03255576_0002; ALLERGAN_MDL_03255576_0005; ALLERGAN_MDL_03255576_0008; ALLERGAN_MDL_03729472
TEVA	TEVA_MDL_A_02401118; TEVA_MDL_A_02416193 - TEVA_MDL_A_02416204; TEVA_MDL_A_02419960; TEVA_MDL_A_02419961; TEVA_MDL_A_02419963- TEVA_MDL_A_02419969; TEVA_MDL_A_08637273-TEVA_MDL_A_08637277
INSYS ⁸	INSYS-MDL-015002410

- d. Peculiar transactions data produced by Mallinckrodt Inc to plaintiffs' counsel through MNK-T1_0008592627 for years 2003, 2005-2017 (there was no data for 2004);
- e. "National Drug Code Dictionary," Drug Enforcement Administration, November 2018 (current version available at www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt);
- f. "NDC Dictionary Instructions," Drug Enforcement Administration, October 2010 (current version available at www.deadiversion.usdoj.gov/arcos/ndc/readme.txt);

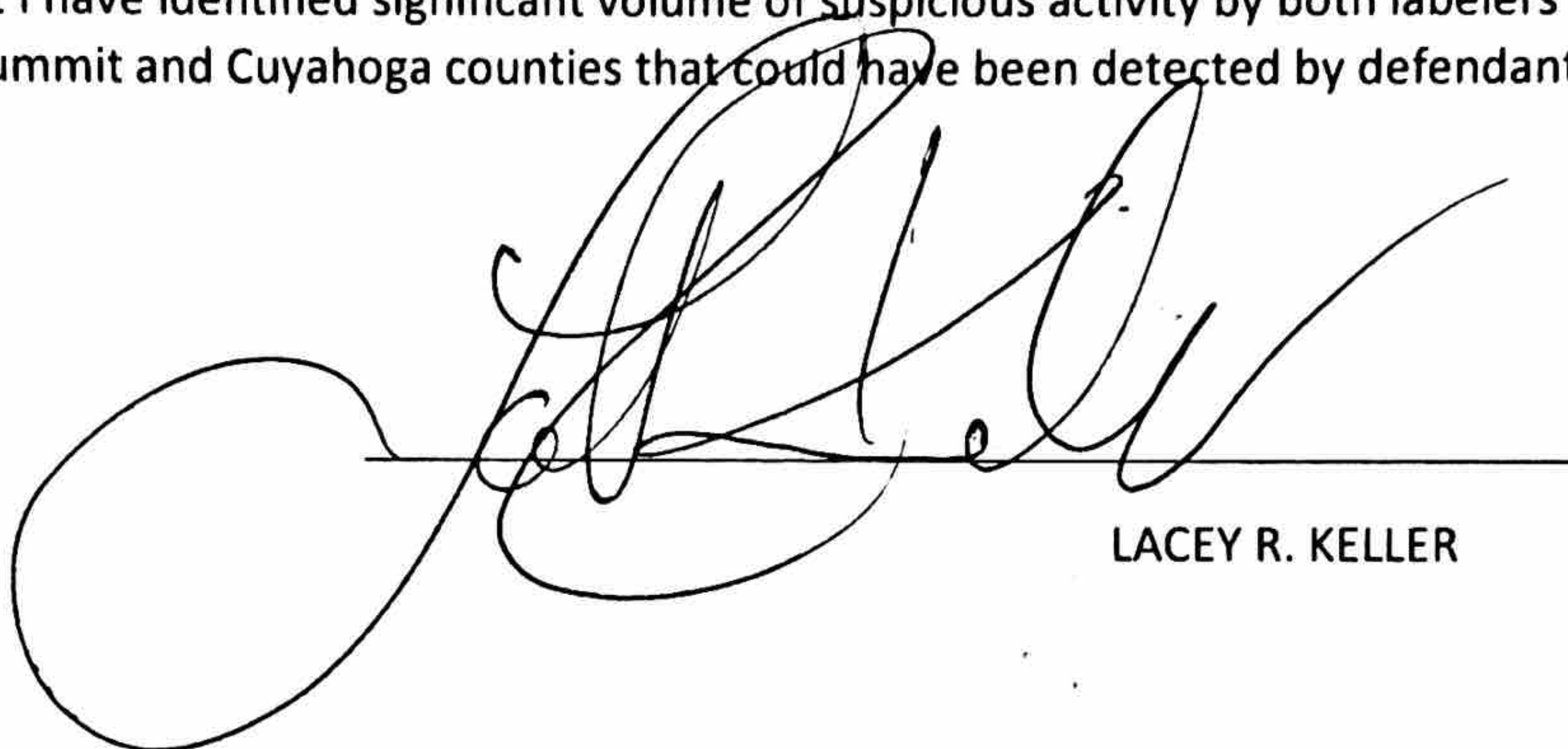
⁶ McCann, Craig J. *National Prescription Opiate Litigation*. MDL No. 2804. 17-MD-2804. 2019.

⁷ Janssen only produced chargeback data for Duragesic and Nucynta for Ohio for years covering 2009 through 2018.

⁸ INSYS produced slightly more than 400 lines of data for the entire state of Ohio for 2014 through 2018.

O. Conclusion

1. Based on my analysis of IQVIA Xponent® data and chargeback data produced by the defendant labelers, I conclude that labelers had sufficient information to assess end buyer prescriptions and purchases.
2. I further conclude that compliance metrics, if properly applied, are capable of capturing patterns of transaction of unusual size or frequency, as illustrated above. Defendant labelers could have leveraged this information to diligently monitor suspicious activity involving defendant labeler opioid products.
3. I further conclude that I have identified significant volume of suspicious activity by both labelers and pharmacies in Summit and Cuyahoga counties that could have been detected by defendant labelers.

A large, stylized handwritten signature in black ink, written over a horizontal line. The signature is cursive and appears to read 'Lacey R. Keller'.

LACEY R. KELLER